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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,104	10/16/2001	Gerald Huber	401301/A.BRAUN	6078

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[REDACTED] EXAMINER

PULLIAM, AMY E

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 03/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/890,104	HUBER ET AL.
	Examiner	Art Unit
	Amy E Pulliam	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 December 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-19 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Preliminary Amendment A, and the Information Disclosure Statement, received by the Office October 16, 2001, and December 18, 2001, respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,178,868 to Malmqvist-Granlund *et al.*. Malmqvist-Granlund *et al.* disclose an oral pharmaceutical formulation made of multiple units containing a pharmacologically active substance, said cores being provided with a coating consisting essentially of a polymer that is insoluble in, impermeable to, and nonsoluble in water and gastrointestinal fluids (abstract). Malmqvist-Granlund *et al.* further teach that the pellets are constituted by a combination of active and excipients, where the pellet consists of cross sectionally substantially homogenous particles, with a diameter between 0.1 and 1.5 mm (c 4, 150-68). Malmqvist-Granlund *et al.* further teach that the active agent incorporated into the pellets can be selected from a large group of actives (c 5, 11-25). Malmqvist-Granlund *et al.* also teach that the polymer used can be cellulose derivatives, acrylic polymers, and vinyl polymers (c 4, 110-15).

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Malmqvist-Granlund *et al.* do not specifically teach that the internal pore diameter does not exceed 35 microns, or that the percent porosity does not exceed 27%. However, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences.

See Ex parte Phillips, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). The cited reference teaches the same general components claimed by Applicant, therefore, the burden is shifted to Applicant to prove that the cited does not possess the claimed characteristics.

Additionally, Malmqvist-Granlund *et al.* do not teach each and every one of Applicant's claimed active agents. However, the reference, like Applicant, teaches that the composition can be used with a wide variety of active agents. Again, the burden is shifted to Applicant to show unexpected results with the use of his particularly claimed active agents.

It is the position of the examiner that Malmqvist-Granlund *et al.* suggest the limitations of Applicant's instant claims. One of ordinary skill in the art would have been motivated to create a pharmaceutical formulation comprising cores of active and excipient, coating with an enteric coating, and made into a dosage form. The expected result would be a controlled release formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Us Patent 4,713,248 to Kjorn es *et al.*. Kjorn es *et al.* disclose an pharmaceutical controlled release multiple units formulation, individual units containing an active substance coated with a substantially water insoluble, but water diffusible coating (abstract). Kjorn es *et al.* teachj that the cores are typically made by granulating particles of the active substance together with excipients, including bulk agents and binders, said cores having a diameter between 0.1 and 1.5 mm (c 7, 120-30). Kjorn es *et al.* further teach that the active substance can be one from a large group of active agents. Kjorn es *et al.* also teach that the coating material can be cellulose esters or acrylic polymers and copolymers (c 8, 135-45-). Lastly, Kjorn es *et al.* teach that the coated units may be incorporated into normal pharmaceutical dosage forms or formulations, such as capsules, sachets or tablets.

Kjorn es *et al.* do not specifically teach that the internal pore diameter does not exceed 35 microns, or that the percent porosity does not exceed 27%. However, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). The cited reference teaches the same general components claimed by Applicant, therefore, the burden is shifted to Applicant to prove that the cited does not possess the claimed characteristics.

Art Unit: 1615

Additionally, Kjorn es *et al.* do not teach each and every one of Applicant's claimed active agents. However, the reference, like Applicant, teaches that the composition can be used with a wide variety of active agents. Again, the burden is shifted to Applicant to show unexpected results with the use of his particularly claimed active agents.

It is the position of the examiner that Kjorn es *et al.* suggest the limitations of Applicant's instant claims. One of ordinary skill in the art would have been motivated to create a pharmaceutical formulation comprising cores of active and excipient, coating with an enteric coating, and made into a dosage form. The expected result would be a controlled release formulation. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THURMAN K PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600